

## REMARKS

Claims 1-20<sup>1</sup> are pending in the present application. Claims 1, 6, 7, 9, and 10 have been amended and claims 3, 4, 5, and 8 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Claims 11-20 have been withdrawn. Support for the foregoing amendment can be found throughout the specification and claims as originally filed, for example on page 3, lines 1-22 and page 6, line 25 through page 7, line 30. No new matter enters by way of the foregoing amendment.

Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

### I. Preliminary Remarks

Prior to addressing the rejections of record, a brief description of the disclosure is provided for the convenience of the Examiner. The disclosure provides a fluid wound dressing composition comprising a partially cured polyurethane fluid. The composition is obtained by mixing: (a) a polyurethane prepolymer comprising an isocyanate capped prepolymer with (b) a curing agent for the polyurethane prepolymer, where the fluid wound dressing composition comprises from about 0.1 wt% to about 4 wt% of unreacted isocyanate. As the present specification discusses, the wound dressing composition provides for “a composition suitable for injection directly into wounds to provide a dressing for the wound.” *Specification* at page 2, lines 27-28. Such compositions are useful in the treatment of cavity wounds, which as discussed in the specification, “can be a problem to treat due to high levels of exudate production, the irregular contours of the wound site, the loss of tissue (sometimes undermining the surrounding skin) and the potential for tracts or sinuses.” *Id.* at page 1, lines 6-8. The wound dressing composition provided in the specification is a liquid, such as a viscous liquid, a paste, or a non-Newtonian fluid. *Specification* at page 3, lines 1-3. “This property makes the wound dressing composition especially suitable for completely filling a cavity wound by injection or pouring, or simply by working the fluid into the wound cavity ... with a spatula or similar implement.” *Id.* at lines 3-5.

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<sup>1</sup> Applicants note that the Office Action erroneously indicates that claims 1-21 are pending. However, claim 21 was cancelled in a preliminary amendment filed on April 25, 2005.

## **II. Restriction/Election**

Applicants affirm the election of Group I (claims 1-10) for further prosecution, as elected during the telephone conference on January 23, 2007. Applicants maintain their traversal as the Patent Office has not proven that the search and examination of the entire application would impose an undue burden. Applicants submit that the complete examination would be handled most expeditiously by treating all of the pending claims as a single entity. As MPEP 803 directs, “[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.” Applicants respectfully submit that the Examiner has not shown that a search and examination of the entire application would cause a serious burden.

## **III. Objections to the Specification and Claims**

The abstract has been objected to for allegedly not being on a single sheet. *Office Action* at page 3. Although it appears that the abstract is contained on a single sheet on page 16 following the claims in the copy of the specification contained in the copy of the PCT Application Serial No. PCT/GB2003/004609 filed on April 25, 2005, to facilitate prosecution, the text of the abstract as contained in PCT Application No. PCT/GB2003/004609 is re-submitted in the above amendment to the specification. Reconsideration and withdrawal of this objection is respectfully requested.

Claim 8 has been objected to for allegedly being in improper dependent form for failing to further limit the subject matter of a previous claim. In view of the amendments to the claims, this objection is moot. Reconsideration and withdrawal of this objection is respectfully requested.

## **IV. Claim Rejections Under 35 U.S.C. § 102(b)**

Claims 1-9 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Szycher U.S. Patent No. 4,614,787 (hereinafter “Szycher”). *Office Action* at page 4. Applicants respectfully traverse for at least the following reasons.

The Examiner asserts with respect to independent claim 1 that “Szycher et al. discloses a wound dressing that is strong and flexible and can be made to conform to the shape of the site of the wound.” *Id.* The Examiner further alleges that “[d]escribed within the

reference the polyurethane cures at room temperature (col. 2, lines 22-24), so it is inherent that the wound dressing composition comprises partially cured polyurethane fluid.” *Id.*

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Szycher et al. lacks at least the features of the amended claims regarding the partially cured polyurethane fluid, for example, where the fluid wound dressing composition comprises from about 0.1 wt% to about 4 wt% of unreacted isocyanate.

Claim 1, has been amended to recite the features originally recited in dependent claims 3 and 5. As amended, claim 1 is directed to a wound dressing composition comprising a partially cured polyurethane fluid obtained by mixing: (a) a polyurethane prepolymer comprising an isocyanate capped prepolymer with (b) a curing agent for the polyurethane prepolymer, where the fluid wound dressing composition comprises from about 0.1 wt% to about 4 wt% of unreacted isocyanate. The Examiner has not shown that the cited reference discloses all of the features of the currently claimed invention. For example, the Examiner has not pointed to any disclosure in Szycher *et al.* that discloses a composition having from about 0.1 wt% to about 4 wt% of unreacted isocyanate.

With respect to the features of claim 3, now incorporated into independent claim 1, the Examiner argues that “Szycher discloses that the major components of the polyurethane composition are a polyol and an [sic] diisocyanate.” *Office Action* at page 4. The Examiner summarizes that “[i]t is inherent that the dressing is at least 50% by weight polyurethane because polyurethane is the main component.” *Id.* Applicants respectfully note that the Examiner has not shown that polyurethane is necessarily present in the composition in an amount of at least 50% by weight. Simply being a “major component” as alleged by the Examiner does not necessarily mean that the composition contains at least 50% by weight polyurethane.

With respect to the features recited in claim 5, now incorporated into independent claim 1, the Examiner alleges that “Szycher et al. disclose that amount of unreacted isocyanate should be low.” *Office Action* at page 5. Applicants respectfully note that Szycher discloses that at “the end of the reaction between the prepolymer and the chain terminator free isocyanate is monitored by infrared spectrophotometry and, if necessary, additional amounts of the chain terminator may be added to scavenge any remaining isocyanate.” The reference emphasizes that “[i]t is important that the low molecular weight monomers present in the composition be reacted prior to contact with the skin” to avoid

apparent toxicity problems. *Szycher et al.*, col 4, lines 36-49. The specification also exemplifies the use of hydroxyethyl methacrylate to scavenge any remaining isocyanate. *Id.* at col. 6, lines 9-14. Accordingly, the Examiner has not shown that Szycher et al. disclose, or even suggest, that the compositions contain *any* unreacted isocyanate in the composition.

Nor would the features lacking in the disclosure of Szycher et al. follow or be inherent from the disclosure of Szycher et al. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). *MPEP* § 2112 IV. Certainly, there is no teaching in Szycher et al. which would indicate that the film discussed in Szycher contains, for example, any unreacted isocyanate in the wound dressing composition.

As the present specification discloses, the wound dressing "comprises a partially cured polyurethane fluid" which comprises at least 50% by weight of the polyurethane components, "but the reaction between the components has not gone to completion." *Specification* at page 3, lines 7-13. The specification further discloses that the composition contains unreacted isocyanate. *Id.* at lines 13-22. There is no teaching in Szycher et al. to include a composition having the recited amount of unreacted isocyanate. Indeed, Szycher et al. disclose that the "[i]t is important that the low molecular weight monomers present in the composition be reacted prior to contact with the skin so that only compounds with molecular weights of 1500-5000 Daltons are present." Szycher et al. go on to note that "[t]he high molecular weight compounds do not leach out of the wound dressing into the underlying tissue and are therefore non-toxic." *See, e.g.*, Szycher et al. col. 4, lines 39-49. As such, the composition disclosed in Szycher et al. does not result in a fluid composition after curing which contains unreacted isocyanate in the recited amounts.

Since the cited reference has not been shown to anticipate amended claim 1, neither does it anticipate dependent claims 2-9. In view thereof and in view of the numerous differences between the features of the amended claims and the disclosure of Szycher *et al.*, Applicant respectfully requests that the rejection of the claims under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

#### **V. Claim Rejections Under 35 U.S.C. § 103(a)**

Claim 10 has been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Szycher *et al.* (U.S. Patent No. 4,614,787) in view of Zamierowski (U.S. Patent No. 4,969,880). *Office Action* at page 6. Applicants respectfully traverse for at least the following reasons.

Amended claim 1, the base claim of claim 10, is directed to a wound dressing composition comprising a partially cured polyurethane fluid obtained by mixing: (a) a polyurethane prepolymer comprising an isocyanate capped prepolymer with (b) a curing agent for the polyurethane prepolymer, where the fluid wound dressing composition comprises from about 0.1 wt% to about 4 wt% of unreacted isocyanate. As discussed above, Szycher *et al.* does not disclose or suggest a fluid composition after curing which contains the recited amounts of unreacted isocyanate. Nor does Zamierowski teach or suggest the use of such compounds in a partially cured polyurethane fluid. As such, the cited references fail to disclose all of the features of the amended base claim from which claim 10 ultimately depends.

The primary reference relied on by the Examiner, Szycher *et al.*, discloses a “wound dressing having a drug dispersed throughout a polyurethane matrix that is the reaction product of: (A) An isocyanate terminated prepolymer formed by reaction of isophorone diisocyanate and a macroglycol and (B) a monomer containing hydroxyl and vinyl groups.” Szycher, *Abstract*. Szycher teaches that the “cured polyurethane elastomer is crystal clear, soft and elastomeric.” *Col. 2, lines 37-38*. The reference further discloses that the elastomer is “[a]ppplied to a wound in the form of a film, [and] the polyurethane serves to release the incorporated drug at a controlled, sustained rate while protecting that portion of the incorporated drug yet to be released.” *Id. at Col. 2, lines 39-42*. The reference discloses that “[i]t is important that the low molecular weight monomers present in the composition be reacted prior to contact with the skin so that only compounds with molecular weights of 1500-5000 Daltons are present.” It goes on to note that “[t]he high molecular weight

compounds do not leach out of the wound dressing into the underlying tissue and are therefore non-toxic.” *See, e.g.*, Szycher et al. col. 4, lines 39-49.

In contrast, the present specification provides a wound dressing composition comprising a partially cured polyurethane fluid. *Specification*, at page 2, lines 24-25. The composition is “suitable for injection directly into wounds to provide a dressing for the wound.” *Id.* at page 2, lines 26-27. As the specification discloses, the “wound dressing according to the present invention is a fluid.” *Id.* at page 3, line 1. In addition, the specification points out that the “fluid may be a liquid, preferably a viscous liquid, or it may be a paste, or it may be a non-Newtonian fluid.” *Id.* at page 3, lines 1-3. Being a liquid provides for a “wound dressing composition especially suitable for completely filling a cavity wound by injection or pouring, or simply by working the fluid into the wound cavity in with a spatula or similar implement.” *Id.* at page 3, lines 3-5.

The Examiner has provided no support that the disclosures of Szycher et al. or Zamierowski would have led one of ordinary skill in the art to combine or modify the teachings therein to obtain the subject matter defined in the amended claims. In view of the foregoing, a *prima facie* case has not been made. There is no motivation to combine and/or modify Szycher et al. or Zamierowski to obtain a wound dressing as currently claimed. Thus, Applicants respectfully request that the rejections of claim 10 under 35 U.S.C. § 103(a) be withdrawn.

## VI. Conclusion

For the foregoing reasons, claims 1-7 and 9-10 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

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